Quantifying the Effect of Pill-taking on Quality of Life

By

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ABSTRACT

Utility measures are used in cost-effectiveness studies to represent the effect a given outcome or intervention has on quality of life. Pills are common interventions used to try to reduce the risk of an adverse health outcome. The utility value for taking pills is often estimated or assumed to be 1.0, suggesting no effect on quality of life, but I wondered whether any studies had been published that quantified this utility value. This master's paper has two goals. In the systematic review portion, I searched for published articles that quantified the utility of taking pills for preventive purposes. In the original research portion, I report the results of a study that quantified the utility value of taking pills to prevent an adverse health outcome.

For the review, I systematically searched PUBMED using strategically selected keywords. This strategy was supplemented with a search of the Cochrane database, a hand search of bibliographies, and questioning of experts. Studies that calculated a utility value were included. I expanded the inclusion criteria to any article that cited a utility value for pill-taking for preventive purposes in adults. In the original research, we invited healthcare system employees to participate in an online survey about taking pills. We calculated mean utility values for taking pills and compared utility values across several demographic characteristics and by numeracy level.

I found two published articles that quantified the utility value of taking aspirin and warfarin. I found a total of nineteen additional published articles that cite a utility value for taking pills for preventive purposes. All these values ranged from 0.95 – 1.0, depending on the type of pills. Through our original research project involving 708 adults, we found that the average utility value for taking one pill per day is 0.997. This

value did not vary significantly by age, sex, race, education level, income level, or number of pills taken per day. Those with low numeracy level tended to have slightly lower utility values.

What is the Effect of Pill-taking on Quality of Life: A Systematic Review of the Utility Value for Taking Pills

ABSTRACT

BACKGROUND: Utility measures are used in cost-effectiveness studies to represent the effect a given outcome or intervention has on quality of life. Pills are common interventions used to try to reduce the risk of an adverse health outcome. The utility value for taking pills is often estimated or assumed to be 1.0, indicating no effect on quality of life, but I was not aware of any studies that specifically aimed to quantify this utility value.

OBJECTIVE: To systematically search for and identify published articles that attempt to quantify the utility of taking pills for preventive purposes.

METHODS: I systematically searched PUBMED using strategically selected keywords. This strategy was supplemented with a search of the Cochrane database, a hand search of bibliographies, and questioning of experts. Studies that cited a utility value were also included.

RESULTS: I found two studies in which investigators interviewed 74 patients and 83 patients and determined the utility values for taking daily aspirin to be 0.998 in both studies and daily warfarin (plus its monitoring) to be 0.987 in one study and 0.988 in the other. I found nineteen additional studies that cited a specific utility value that varied from 0.95 to 1.0, depending on the type of pill and whether or not side effects and/or drug monitoring were included in the utility value.

CONCLUSIONS: I found two studies that quantified a utility value for pill-taking, although both studies were limited by a small sample size.

INTRODUCTION:

Most adults will end up taking daily pills at some point in their lives. Many adults take multiple pills, often more than once per day. When people take pills they must go through a process that involves, but is not limited to, obtaining the pills, paying for them, ingesting the pills, dealing with any side effects which the pills may cause, and remembering to take the pills. If the pills require a prescription, the process also includes visits to clinicians and pharmacists. These processes, part of the routine of "taking pills," can theoretically affect quality of life.

When people take pills on a daily basis, they do so either to try to prevent an undesired health outcome or to treat a specific condition and/or its symptoms. In both cases, there may be some diminution in quality of life. Side effects of pills aside, the effects of pill-taking on quality of life are likely to vary not only based on the reason people take pills but also on other factors such as number of pills taken per day, number taken at one time, and even the size of the pills. In health studies, effects on quality of life are often measured by assigning a numerical value that represents the relative quality of life effect that a certain health state carries versus a standard state. This numerical value is termed a "utility." Utilities range from 0 to 1, with 0 representing death and 1 representing perfect health.

There are many studies that address patient adherence and compliance based on quantity and complexity of prescribed medication regimens, as well as studies that attempt to quantify patient utilities for outcomes of certain diseases.[1-3] However I was unaware of any study that quantified the utility value of taking pills. The overarching goal of this systematic review was to identify published studies that either specifically

sought to quantify how the act of taking pills affects quality of life or that used a specific utility value of taking pills as part of the study.

METHODS

Eligibility Criteria

I sought any study that met the following criteria: (1) human subjects older than 18 years, and (2) determined a utility value of taking pills. Because of an initial low yield of such studies, I expanded the review to include any study that used a utility value for taking pills. Non-English language studies were excluded.

Search Strategy

To identify relevant studies, a search of the MEDLINE database was conducted using the following search: ((((cost-utility[Title]) OR cost-effectiveness[Title]))) AND (((prophylaxis[Title]) OR prevention[Title])). This strategy was supplemented with a search of the Cochrane database, a hand search of bibliographies, and questioning of experts. I reviewed the titles and abstracts of the articles identified by the searches, as well as any relevant *Methods* sections, and excluded the studies that did not meet eligibility criteria.

Data Abstraction

Data abstracted from relevant studies included study design, year, country, medication regimen, utility value, utility range (if given), and the method of utility assessment.

RESULTS

A PubMed search yielded 779 results. After exclusion of non-English and non-Human results, 643 results remained. After reviewing the titles, abstracts, and methods sections, 12 results remained. A hand search of those 12 studies' references yielded another 8 results that had not already been reviewed. (Figure 1)

Two studies were found that included a systematic method to quantify the utility of taking pills.[4-5] In the first study, the investigators interviewed 74 subjects about preferences for various health states as well as taking daily aspirin and warfarin.[4] Some subjects were unable to understand the time trade-off concept so they were excluded from the analysis, leaving a sample size of 57 subjects. Utilities for taking pills were assessed using a computerized utility assessment tool utilizing the time trade-off method. The mean utility value for taking aspirin was 0.998, and the mean utility for taking warfarin was 0.988. It is important to note that the utility value for taking warfarin included the utility of the routine therapeutic monitoring (i.e., INR checks) every 4 weeks, avoiding contact sports and avoiding excessive alcohol consumption. Similarly, in the second study, the investigators interviewed 83 subjects using a time trade-off method to assess the utility value of taking aspiring and warfarin, as well as other health states.[5] Thirteen subjects were excluded due to either difficulty understanding the time trade-off concept, inability to understand 1 or more questions, or time constraints for the interview. Responses of the 70 remaining patients were analyzed and the mean utility value for taking aspirin was 0.998, and the mean utility value for taking warfarin was 0.987.

A total of eighteen (18) additional studies were found that *cite* an estimated utility value of taking pills.[3,6-22] These were located by initial review and by hand

searching bibliographies and questioning experts. All studies included in this review cited a utility value between 0.95 – 1.0, varying depending on the type of medication, whether or not side effects of the medication are considered, and in the case of anti-coagulants, whether INR monitoring is considered (Table). Additionally, all of the studies except two were either decision analyses, or analyses of cost-effectiveness, cost-benefit, or comparative-effectiveness of taking a medication for a specific purpose on a daily basis. The medications included in the studies were: aspirin,[4-8,10,12-19,21] warfarin, [4-5,8-10,12-15,21] statins,[11,17,20] anti-hypertensives,[3,22] aspirin + clopidogrel,[7,21] apixaban,[12,19] rivaroxaban,[13,19] ximelagatran,[15] and dabigatran.[10,19,21] The studies varied on their source for the utility value. Most of these studies derived their utility value from another study included in this review; [6-16,19,21] one did not specifically cite a reference for its utility values;[17] another three used the author's judgment; [3,18,20] and one used physician surveys.[11]

DISCUSSION

In this systematic review, I found two studies whose primary goals included attempting to quantify a specific utility value or range of utility values for taking pills,[4-5] though both of these studies was limited by small sample sizes of 57 and 70. The studies determined two utility values that differed based on the type of medication, aspirin or warfarin. Additionally, I found eighteen other studies that cited a specific utility value.[3,6-22] The utility values varied from 0.95 to 1.0, the latter of which would indicate no quality of life effect of taking pills, which is unlikely. Although the utility value for taking pills is certainly less than 1.0, it is likely very close to 1.0, as most of the included studies

suggest. Deriving a precise value for the utility of taking pills would be important not only for issues of clinical decision making, but also pharmaceutical research, health policy, and cost-effectiveness research. One study included in this review discussed whether cost-effectiveness of taking aspirin for cardiovascular disease prevention was sensitive to the assigned utility of the pill.[16] For their base case, the authors used a utility value of 1.0. Then they examined and reported the cost per quality-adjusted life-year (QALY) gained across a variety of potential utility values. In their analysis, using a utility value of about 0.9996 caused an increase in the cost per QALY above the accepted cost-effective threshold of $50,000/QALY. Their study demonstrates the importance of having an accurate utility value when calculating cost-effectiveness.

Limitations

The key limitation to this review is that a variety of different terms are used to refer to the actual utility value for which I was looking. For example, "utility" is sometimes described as *disutility, quality of life, health effect,* and *health-related quality of life.* This variation made it difficult to find applicable studies that include a utility value. Therefore, there are likely additional studies that refer to a utility value of taking pills that were not found upon the literature search for this systematic review.

Future Research

Given the lack of direct assessment of the utility value of taking pills, a beneficial topic of future research would be a specific patient-centered assessment of this utility value. Determination of the utility value applied by patients will likely vary depending on specific pill characteristics, side effects, patient difficulty in obtaining medication

(including costs), quantity of pills taken, reason for taking the pills, as well as the specific utility measurement tool used.

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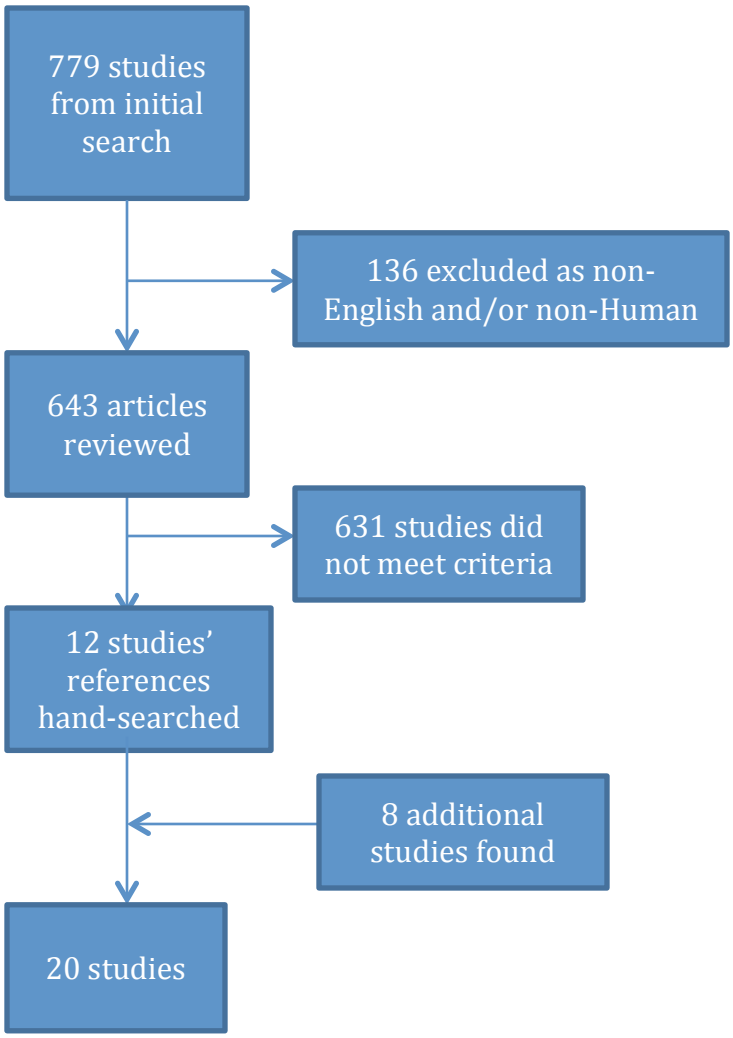

Figure. Study selection

Table. Studies Included in Review

Study	Utility Value	Medication Type	Utility Range	Study Type	Comments
Augustovski, et. al	0.999	Aspirin	0.985 – 1.0	Decision analysis	Cites: Naglie
Coleman, et. al	0.996 0.987	Aspirin Clopidogrel+ Aspirin	0.95 – 1.0 0.95 – 1.0	Cost-effectiveness analysis	Cites: Gage (1996), O'Brien, Freeman; Estimate for Clopidogrel+ Aspirin
Davidson, et. al	0.998 0.987	Aspirin Warfarin	None given	Cost-effectiveness analysis	Cites: Gage (1996)
Eckman, et. al	0.99	Warfarin	None given	Cost-effectiveness analysis	Cites: Gage (1996)
Freeman, et. al	0.998 0.994 0.987	Aspirin Dabigatran Warfarin	0.994 – 1.0 0.975 – 1.0 0.953 – 1.0	Cost-effectiveness analysis	Cites: Gage (1996), O'Brien
Gage, et. al (1995)	0.998 0.988	Aspirin Warfarin	0.96 – 1.0 0.92 – 1.0	Cost-effectiveness analysis	57 patient interviews using time trade-off method
Gage, et. al (1996)	0.998 0.987	Aspirin Warfarin	0.994 – 1.0 0.953 – 1.0	Cross-sectional study with patient interviews	70 patient interviews using time trade-off method
Greving, et. al	0.999	Statin	None given	Cost-effectiveness analysis	Cites: Pignone (2006), Augustovski, Naglie
Lee, et. al	0.998 0.994 0.987	Aspirin Apixaban Warfarin	0.994 – 1.0 0.975 – 1.0 0.940 – 1.0	Cost-effectiveness analysis	Cites: Freeman
Lee, et. al	0.998 0.994 0.987	Aspirin Rivaroxaban Warfarin	0.994 – 1.0 0.975 – 1.0 0.940 – 1.0	Cost-effectiveness analysis	Cites: O'Brien, Gage (1996)
Naglie, et. al	0.999 0.990	Aspirin Warfarin	0.985 – 1.0 0.95-1.0	Decision analysis	Cites: Torrance, Weinstein
O'Brien, et. al	0.998 0.987 0.989	Aspirin Warfarin Ximelagatran	0.994 – 1.0 0.953 – 1.0 0.986 – 0.991	Cost-effectiveness analysis	Cites: Gage (1996)

	0.994	(< 6 months) Ximelagatran (> 6 months)	0.993 – 0.996		Ximelagatran utilities from physician survey
Pignone, et. al (2006)	1.0 1.0	Aspirin Statins	Used for sensitivity analysis, but range not given	Cost-utility analysis	No reference given; Utility value varied in sensitivity analysis
Pignone, et. al (2007)	1.0	Aspirin	Used for sensitivity analysis, but range not given	Cost-utility analysis	Cites: Naglie; Utility value varied in sensitivity analysis
Pignone, et. al (2013)	0.999	Aspirin		Cost-utility analysis	Assumption
Pink, et al.	0.998 0.998 0.998 0.998 0.987	Aspirin Apixaban Dabigatran Rivaroxaban Warfarin	Probabilistic sensitivity analysis, but range not given	Comparative effectiveness analysis	Cites: Gage (1996)
Pletcher, et. al	1.0	Statins	None given	Cost-effectiveness analysis	Clinical judgment
Shah, et. al	0.998 0.998 0.987 0.994	Aspirin Aspirin + Clopidogrel Warfarin Dabigatran	0.994 – 1.0 0.994 – 1.0 0.953 – 1.0 0.990 – 0.998	Cost-effectiveness analysis	Cites: Gage (1996)
Torrance, et. al (1987)	0.95 – 0.99	Anti-hypertensives	0.95 – 0.99	Original Article	Author's judgment
Weinstein and Stason	0.99	Anti-hypertensives	None given	Cost-utility analysis	

Quantifying the Utility of Taking Pills for Preventing Adverse Health Outcomes

ABSTRACT

BACKGROUND: Utility measures are used in cost-effectiveness studies to represent the effect a given outcome or intervention has on quality of life. Pills are common interventions used to try to reduce the risk of an adverse health outcome. The utility value for taking pills is often estimated or assumed to be 1.0, indicating no effect on quality of life, but to our knowledge there are few published studies that have systematically quantified this utility value.

OBJECTIVE: To quantify the utility value of taking pills to prevent an adverse health outcome.

METHODS: We invited healthcare system employees to participate in an online survey about taking pills. The main outcome variables were utility values for taking one pill per day, two pills per day, and one pill twice daily, all assessed using time trade off. We also assessed utility value for taking one pill per day using standard gamble and willingness-to-pay methods. We compared utility values across several demographic characteristics and by numeracy level.

RESULTS: A total of 708 adults completed the survey. Mean age of respondents was 43 years. The majority of the respondents were female (83%) and Caucasian (80%). Almost all participants had health insurance (99%), and about 84% had at least an adequate numeracy level. Most (80%) took at least two pills per day. Mean utility values using the time trade-off method were: 0.9972 (95% CI 0.9962-0.9981) for one pill daily, 0.9969 (95% CI 0.9957-0.9979) for two pills daily, and 0.9965 (95% CI 0.9955-0.9975) for taking 1 pill twice daily. The utility values for taking 1 pill daily using the standard

gamble and willingness-to-pay methods were 0.9968 (0.9955-0.9980) and 0.9985 (95% CI 0.9982-0.9988), respectively. Mean utility values did not vary significantly by age, sex, race, education level, income level, or number of pills taken per day. Those with low numeracy level tended to have slightly lower utility values.

CONCLUSIONS: The utility value of taking pills daily in order to prevent an adverse health outcome is approximately 0.997, varying slightly depending on the pill regimen and utility assessment method used.

INTRODUCTION

The desire to take medicine is perhaps the greatest feature which distinguishes man from animals. – Sir William Osler

Most adults will end up taking daily pills at some point in their lives. Many adults take multiple pills, often more than once per day. When people take pills they must go through a process that involves, but is not limited to, obtaining the pills, paying for them, ingesting the pills, and remembering to take the pills. These processes, part of the routine of "taking pills," can theoretically affect quality of life. If the pills require a prescription or therapeutic monitoring, the process also includes visits to clinicians and pharmacists, which may further affect quality of life.

When people take pills on a daily basis, they do so either to try to prevent an undesired health outcome or to treat a specific condition and/or its symptoms. In both cases, there may be some diminution in quality of life attributable to pill-taking. Side effects of pills aside, the effects of pill-taking on quality of life are likely to vary not only based on the reason people take pills but also on other factors such as number of pills taken per day, number taken at one time, and even the size of the pills. In health studies, effects on quality of life are often measured by assigning a numerical value that represents the relative quality of life effect that a certain health state carries versus a standard state. This numerical value is termed a "utility." Utilities usually range from 0 to 1, with 0 representing death and 1 representing perfect health.

There are many studies that address patient adherence and compliance based on quantity and complexity of prescribed medication regimens, as well as studies that attempt to quantify patient utilities for outcomes of certain diseases.[1-3] However, we are

aware of only two studies that included a systematic effort to quantify the utility value of taking pills.[4-5] In those studies, 57 and 70 patients were interviewed, and using the time trade-off utility assessment method, the investigators found a utility value of 0.998 for taking daily aspirin in both studies and 0.987 for taking warfarin (including monitoring) in one study and 0.988 for taking warfarin in the second study. There are additional studies that cite a utility value or discount value to taking pills,[3,6-22] though some of these studies seem to have chosen values arbitrarily, based on expert opinion, or based on other published articles.

We conducted a cross-sectional study using an electronic survey to quantify the utility of taking pills for the purpose of trying to prevent an adverse health outcome. Secondarily, we sought to understand whether the average utility value varies by demographics and other characteristics. Knowing this information will be useful for researchers conducting cost-effectiveness analyses or studying the utility of combination medications. Additionally, this information may inform interventions designed to improve adherence to medication regimens.

METHODS

Survey Development

We used a focus group composed of eight people to guide the framing of the utility questions for our survey. Specifically, we tested each of the utility value measurement methods: rating scale, time trade-off (TTO), willingness-to-pay (WTP), and standard gamble (SG). When asked test questions using the rating scale method (e.g., a scale of 0 to 100), it was clear that focus group participants were overestimating the

utility of taking pills, often assigning utility values of 0.7 or lower to taking one pill per day – a value which would be comparable to non-disabling stroke (0.75).[4] The WTP method also proved difficult as a measure for pill-taking utility due to most participants not being willing to pay anything for an alternative health state. The standard gamble was a difficult concept for focus group participants to grasp, but feedback was used to refine an SG question. The time trade-off method seemed to be the best understood method by the focus group participants, providing a range of responses we considered most consistent with the likely value for the utility of taking pills.

Our survey (Appendix) was created using Qualtrics and consisted of initial questions about the respondent's personal pill regimen, as well as questions about how specific qualities of pills (e.g., size, shape) affect the difficulty of taking a pill. Following this initial section, we transitioned into the utility measurement section using a series of time trade-off method questions. We also included two additional questions to assess utility via a willingness to pay method and a standard gamble method. We included questions in order to ascertain numeracy level of each respondent, followed by a final section asking for basic demographic information.

We pilot tested the survey using a convenience sample to gather feedback on ease of completion and clarity of questions. Based on feedback, we refined a few items to maximize clarity. The study was granted exempt status by the Office of Human Research Ethics of the University of North Carolina at Chapel Hill.

Participant Selection

An informational email advertising the study and asking for volunteers was sent to all UNC Healthcare employees. Additionally, an informational newsletter ad was placed in the UNC Healthcare employee newsletter and the UNC School of Medicine employee newsletter. An estimated total of 18,500 people were sent the advertisement either by email announcement (8,592) or by newsletter ad (10,000). The only criterion for eligibility was age 18 years or older.

Variables

The main outcome variables for this study were utility values for taking one pill per day, two pills daily, and one pill twice daily. These values were all obtained using a time trade-off utility assessment method. We also obtained a utility value for taking one pill per day using both the standard gamble and willingness-to-pay methods. Participants rated difficulty obtaining medications and difficulty paying for medications on a scale from 1 to 5. For analysis, these were then combined into three categories: not difficult, neutral, and difficult. Additionally, numeracy was assessed using a 3-question numeracy questionnaire, with overall numeracy level then categorized as either "low" if the respondent got 0-1 correct answers or "adequate" if the respondent got 2-3 answers correct.[23]

Data Analysis

Participant responses to time trade-off, standard gamble and willingness-to-pay questions were converted to utility values using Microsoft Excel, after which an analysis

was performed using STATA 12 (College Station, TX). The TTO utility value was derived by calculating the proportion of time that each respondent was willing to give up by the amount of time each respondent had left in his or her life (using an average life expectancy of 78 years) and subtracting from 1. Some survey respondents did not enter age in the survey, which prevented us from being able to calculate a time trade-off utility value. Those participants with missing age data (n=95) were excluded from the time trade-off utility analysis.

The utility value for SG was calculated as 1 minus the risk of death the participant was willing to accept for the alternate treatment. The utility value using WTP was derived by dividing the amount a participant was willing to pay (to not have to take a pill) by their total estimated earnings through an average retirement age of 65 years and subtracting from 1. We excluded all participants who did not provide an age (n=95) and those who were older than 65 (n=19). We used the middle value from whichever income category the participant selected. The responses received for WTP varied significantly in range, which led to some utility values being considerable outliers. Therefore, we also excluded WTP utility values below 0.95 (n=4). A total of 118 responses were excluded from the WTP analysis.

We describe basic participant demographics ratings of pill characteristics and average utility values using proportions with 95% confidence intervals or means with standard deviations. One-way ANOVA was used to compare utility values by participant characteristics. All utility values were rounded to four decimal places. A p-value ≤ 0.05 was used to define statistical significance.

RESULTS

Characteristics of Respondents

A total of 758 people opened the survey link, with 9 who denied consent. Of the 749 who gave consent and began the survey, 708 finished the survey before it was closed (Figure 1). The rate of completion among all who were sent an advertisement about the study was 708/18,500 (~3.8%). Mean age of respondents was 43 years, with more participants in the >50 year old category (41%) than either the 18-35 (30%) or the 36-50 (29%) year old categories (Table 1). Most participants were female (83%) and Caucasian (80%), while almost all participants had health insurance (99%). Additionally, almost half of the participants had annual household incomes greater than $75,000 (48%) while about 85% had at least a college degree. Based on a set of three numeracy questions, 84% had adequate numeracy and 61% rated their health as very good or excellent. Less than 8% of participants reported any degree of difficulty obtaining their pills, while about 16% of participants reported some degree of difficulty paying for their pills. Approximately 65% took at least 3 pills per day, while only 3.7% took no pills per day (Table 1).

Pill Characteristics

Pill size was the most important characteristic affecting difficulty of pill-taking, with a mean score of 3.06 on a scale of 1 to 5 where 5 represents the greatest influence on difficulty (Table 2). Shape was the least important characteristic with a mean score of 2.23.

Time Trade-Off Utility Value

The overall average utility value using time trade-off revealed a utility of 0.9972 for taking 1 pill daily, 0.9969 for taking 2 pills daily and 0.9965 for taking 1 pill twice daily (Table 3). Mean utility value was not significantly different by age, sex, race, education level, or income level (Table 4). When considering 2 pills daily and one pill twice daily, respondents with low numeracy level had slightly lower mean utility values compared to those with adequate numeracy level. There also appeared to be slight differences based on difficulty obtaining pills. Although not statistically significant, the small number of respondents who indicated currently taking no daily pills did have a lower mean value for utility of taking pills than those who took at least 1 pill per day.

Standard Gamble Utility Value

Using a standard gamble method, the overall average utility value for taking 1 pill daily was 0.9968 (Table 3). Mean utility value by SG also did not vary by age, sex, race, education level, or self-reported health status (Table 5). As with the TTO, those who took no daily pills assigned a lower utility value to taking pills than those who took at least 1 pill per day, although the difference was not statistically significant. Again, those with lower numeracy level assigned a lower mean utility value (0.9919 vs. 0.9976, $P<0.01$).

Willingness-to Pay Utility Value

Using a willingness-to-pay utility assessment method, the overall average utility for taking one pill daily was 0.9985 (Table 3). With WTP, those in the higher age group and those with lower income both had lower mean utility values (Table 5).

DISCUSSION

The primary goal of this study was to quantify a specific utility value of taking pills. We hypothesized that there is some diminution in quality of life attributable to pill-taking, but that it would be small. Based on our results, we are confident that a reasonable utility value for taking a pill daily to try to prevent an adverse health outcome is 0.997. The 95% confidence interval for this value is 0.996 to 0.998, and this value appears to hold across multiple comparison groups. People who do not take pills on a daily basis may rate the act of taking a pill on quality of life as having a greater impact (i.e. lower utility) than those who actually do take pills on a daily basis. Although our sample size for this subgroup was small, this finding suggests that moving from a state of taking no pills to a state of having to take daily pills may be viewed as having a larger effect (though still small overall effect) on quality of life than transitioning from other states (e.g., 1 pill to 2 pills).

Our results are comparable to two prior studies that measured a utility value for pill-taking.[4-5] Our utility value of 0.997 is similar to the value of 0.998 found in both prior studies for taking aspirin. However, our value is higher than the values for taking warfarin noted in prior studies: 0.987 and 0.988. This difference is likely due to the fact that those studies included within the utility of taking the pill the additional utility of the

INR monitoring and lifestyle limitations such as avoidance of excessive alcohol and contact sports. We sought to examine the utility of pill-taking itself, viewing aspects such as bothersome side effects, limitations, and any required therapeutic monitoring as separate issues.

We are aware of at least nineteen additional studies that *use* a utility value of taking pills in their analyses. All of the studies cited values between 0.95 and 1.0, depending on the type of pill and whether or not side effects and monitoring were considered.[3-22] Most of the analytic studies used a value close to 1.0 as their base case and then performed a sensitivity analysis to analyze a range. The lower end of their range was generally lower than the values that we obtained in this study.

A very small change in the utility value assigned to pill-taking can have an important effect on cost-effectiveness results. For example, one study examined whether cost-effectiveness of aspirin was sensitive to the assigned utility value of taking the pill.[16] The base case used a utility value of 1.0; the authors then examined the cost per quality-adjusted life-year (QALY) gained across a variety of utility values for taking aspirin. In that analysis, using any utility value below about 0.9996 caused an increase in the cost per QALY above the accepted cost-effective threshold of $50,000/QALY. Such an analysis highlights the importance of having an accurate utility value for pill-taking.

As expected, as the pill regimen becomes more complex and time-consuming, the utility decreases. From one pill daily to two pills daily to one pill twice daily, the utility value incrementally decreased from 0.9972 to 0.9969 to 0.9965, respectively, using the TTO method (Table 3). The SG method and WTP method both revealed similar values of 0.9968 and 0.9985, respectively. These findings, along with our results in Table 2,

suggest that two things that can be done to minimize the impact of pill-taking on quality of life are keeping pill regimens simple (i.e., once daily) and making pills small in size.

Limitations

There are several limitations we acknowledge. First, individuals who are eligible to receive informational emails and the newsletter can easily opt out using their email filter. Additionally, many people simply delete informational emails upon receipt into their email inbox. Therefore, we don't know precisely how many people actually received the email and opened it. If the people who did not participate had answered the utility questions differently than people who did respond, we would have a nonresponse bias. Our respondents were predominantly women, although we saw no differences in utility values by sex. Our respondents were geographically isolated to the Chapel Hill, North Carolina area. Although unlikely, it is possible that utility values could vary by geographic region. Our WTP analysis did not account for any participants over the age of 65 years and also does not account for any income over age 65, which is not likely. It also assumes that a person's annual income remains stable over a lifetime, which is also unlikely. We therefore have the least confidence in the estimates generated by WTP.

Conclusion

The utility value of taking a pill daily to prevent an adverse health outcome is approximately 0.997. Knowing this value is useful for researchers who conduct cost-utility analyses. It is also relevant to the pharmaceutical industry in considering what

people might be willing to pay for combination pills. Finally, this study reminds clinicians that patients appreciate once-daily pill regimens and small pills.

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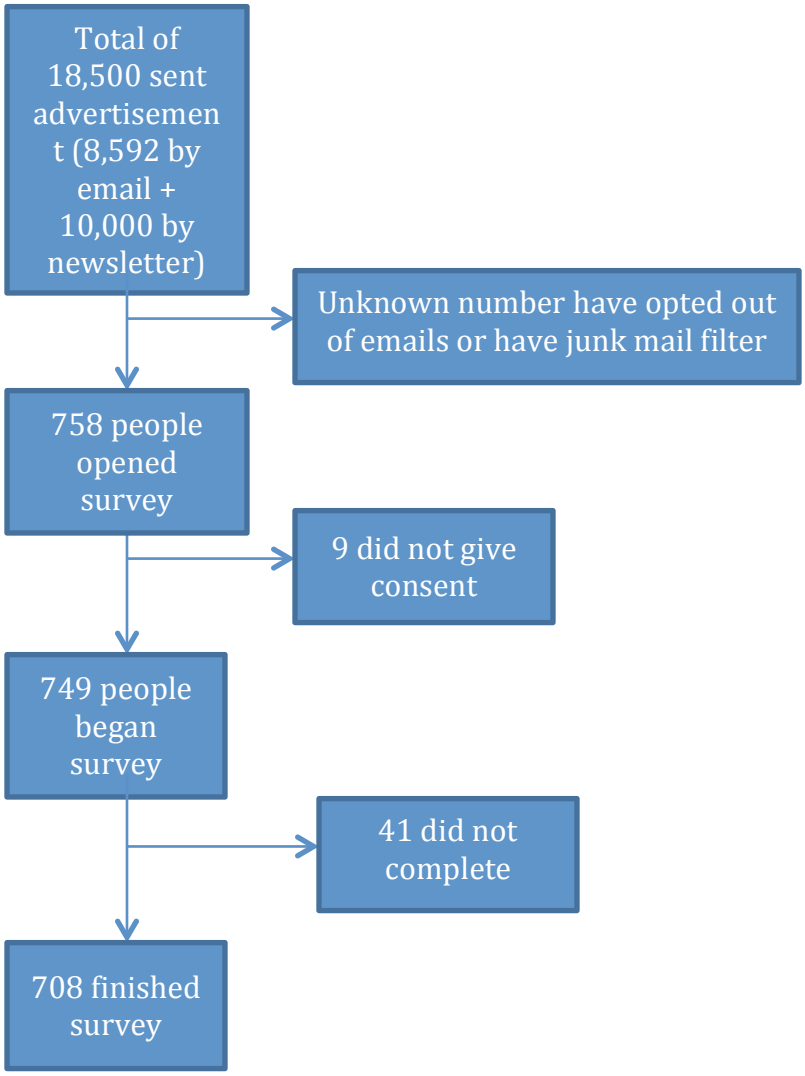

Figure 1. Study Participation

Table 1. Participant Characteristics

Characteristic	n	Number or Percent
Mean age	613	43 years
Age group	613	
18-35 years		29.8%
36-50 years		29.1%
>50 years		41.1%
% Female	708	83.3%
Race	708	
Caucasian		79.8%
African American		11.3%
Other		8.9%
Income	708	
< $25,000		6.1%
$25,000 - $75,000		45.6%
>$75,000		48.3%
< College degree	708	14.7%
Numeracy	708	
0 correct		4.4%
1 correct		11.9%
2 correct		32.6%
3 correct		51.3%
Health*	708	
Poor		0.6%
Fair		7.2%
Good		31.5%
Very Good		44.8%
Excellent		16.0%
% Insured	708	98.6%
Difficulty obtaining pills §	708	
Somewhat difficult		7.3%
Very difficult		0.4%
Difficulty paying for pills §	708	
Somewhat difficult		15.0%
Very difficult		1.1%
# times pills taken per day ≥ 2	708	50.6%
# pills taken per day	708	
0		3.7%
1		16.0%
2		15.5%
3+		64.8%

* Self-reported

§ Rated on 5 point scale

Table 2. Participant Rating of Importance of Characteristics of Pills

Characteristic of Pill	Mean Rating* (SD)
Size	3.06 (1.55)
Cost	2.74 (1.46)
Taste	2.66 (1.44)
Smell	2.33 (1.39)
Coating	2.31 (1.34)
Shape	2.23 (1.33)

* Rated on 5 point scale with 1 indicating that the characteristic does not affect the difficulty of taking a pill at all and 5 indicating that the characteristic greatly affects the difficulty of taking a pill

Table 3. Average Utility Value for Each Outcome

Assessment Method	Utility Value (95% CI)
Time Trade-Off *	
1 Pill Daily	0.9972 (0.9962-0.9981)
2 Pills Daily	0.9969 (0.9957-0.9979)
1 Pill Twice a Day	0.9965 (0.9955-0.9975)
Standard Gamble	
1 pill daily	0.9968 (0.9955-0.9980)
Willingness-to-pay € §	
1 pill daily	0.9985 (0.9982-0.9988)

* Participants with missing age data removed prior to calculating mean and SD (95 responses removed)

€ Participants with missing age data (n=95) and age ≥ 65 (n=19) removed prior to calculating mean and SD (114 responses removed)

§ Outliers below 0.95 were removed from data prior to calculating mean and SD (4 responses removed)

Table 4. **Mean Utility Values by Participant Characteristics ^**

Characteristic	n	1 pill daily		2 pills daily		1 pill twice daily	
		Mean	p value*	Mean	p value*	Mean	p value*
Age (years)							
18-35	211	0.9987	0.07	0.9983	0.0929	0.9975	0.31
36-50	206	0.9962		0.9957		0.9957	
>50	196	0.9966		0.9965		0.9962	
Sex							
Female	519	0.9974	0.25	0.9970	0.59	0.9966	0.60
Male	94	0.9959		0.9963		0.9959	
Race							
African American	68	0.9964	0.56	0.9954	0.43	0.9949	0.28
Caucasian	492	0.9974		0.9972		0.9969	
Other	53	0.9959		0.9959		0.9949	
Education Level							
< College Degree	84	0.9974	0.88	0.9971	0.88	0.9970	0.68
College or Graduate degree	529	0.9972		0.9969		0.9964	
Income							
< $25,000	33	0.9953	0.64	0.9945	0.50	0.9943	0.54
$25,000 - $75,000	277	0.9972		0.9969		0.9965	
>$75,000	303	0.9974		0.9971		0.9968	
Health Rating							
< Very Good	227	0.9967	0.42	0.9961	0.26	0.9963	0.74
≥ Very Good	386	0.9975		0.9973		0.9966	
Numeracy Level ∞							
Low	93	0.9952	0.08	0.9936	< 0.01	0.9941	0.04
Adequate	520	0.9975		0.9975		0.9969	
Difficulty Obtaining Pills							
Not difficult	517	0.9976	0.01	0.9973	0.09	0.9968	0.28
Neutral	51	0.9924		0.9935		0.9939	
Difficult	45	0.9978		0.9957		0.9966	
Difficulty Paying for Pills							
Not difficult	435	0.9978	0.01	0.9977	0.01	0.9971	0.04
Neutral	83	0.9935		0.9933		0.9933	
Difficult	95	0.9979		0.9965		0.9966	
# times pills taken per day							
< 2	303	0.9963	0.08	0.9961	0.14	0.9955	0.04
≥ 2	310	0.9980		0.9976		0.9975	
# pills taken per day							
0	25	0.9936	0.28	0.9944	0.61	0.9941	0.53
1	99	0.9969		0.9966		0.9956	

2	96	0.9987		0.9980		0.9976	
3+	393	0.9971		0.9968		0.9966	

^ Utilities derived using time trade-off technique

* p values based on one-way analysis of variance

∞ Numeracy level based on number of questions correct on numeracy question (0-1 = Low; 2-3 = Adequate)

Table 5. Mean Utility Value of Taking 1 Pill Daily by Participant Characteristics^

Characteristic	Standard Gamble			Willingness-to-Pay € §		
	n	Mean	p value*	n	Mean	p value*
Age (years)						
18-35	211	0.9966	0.81	210	0.9995	< 0.01
36-50	206	0.9973		205	0.9987	
>50	291	0.9963		175	0.9971	
Sex						
Female	590	0.9966	0.62	493	0.9984	0.04
Male	118	0.9974		97	0.9993	
Race						
African American	80	0.9934	0.14	68	0.9981	0.41
Caucasian	565	0.9973		469	0.9986	
Other	63	0.9957		53	0.9981	
Education Level						
< College Degree	104	0.9950	0.25	80	0.9988	0.47
College or Graduate degree	604	0.9970		512	0.9985	
Income Level						
<$25,000	43	0.9971	0.97	36	0.9967	< 0.01
$25,000-$75,000	323	0.9966		273	0.9982	
>$75,000	342	0.9968		281	0.9990	
Health Rating						
< Very Good	278	0.9964	0.74	233	0.9984	0.71
≥ Very Good	430	0.9969		357	0.9986	
Numeracy Level ∞						
Low	115	0.9919	< 0.01	67	0.9986	0.79
Adequate	593	0.9976		523	0.9985	
Difficulty Obtaining Pills						
Not difficult	594	0.9971	0.13	500	0.9985	0.09
Neutral	59	0.9962		48	0.9975	
Difficult	55	0.9925		42	0.9993	
Difficulty Paying for Pills						
Not difficult	493	0.9976	0.01	418	0.9986	0.15
Neutral	101	0.9969		80	0.9977	
Difficult	114	0.9925		92	0.9986	
# times pills taken per day						
< 2	350	0.9961	0.34	295	0.9988	0.10
≥ 2	358	0.9973		295	0.9982	
# pills taken per day						
0	26	0.9953	0.49	25	0.9994	0.27
1	113	0.9965		97	0.9985	
2	110	0.9989		94	0.9991	
3+	459	0.9963		374	0.9983	

^ Utilities derived using standard gamble technique or willingness-to-pay technique, as indicated

* p values based on one-way analysis of variance

€ Participants with missing age data (n=95) and age ≥ 65 (n=19) removed prior to calculating mean and SD (114 responses removed)
§ Outliers below 0.95 were removed from data prior to calculating mean and SD (4 responses removed)
∞ Numeracy level based on number of questions correct on numeracy question (0-1 = Low; 2-3 = Adequate)

APPENDIX. Survey Items.

What is the effect on quality of life of taking pills?

What is your age? _____

We'd like to start by asking you a few questions about taking pills, which includes capsules, tablets, or gelcaps.

How many pills do you take each day? (Include vitamins and prescription medications you take daily but not pills you take only once in a while)

- 0 (skip next three items)
- 1
- 2
- 3
- 4
- 5
- 6 or more

How many different times a day do you regularly take pills?

- Once per day
- 2 times per day
- 3 times per day
- More than 3 times per day

How difficult is it for you to pay for your pills?

- Very difficult
- Somewhat difficult
- Neutral
- Not very difficult
- Not difficult at all

How difficult is it for you to obtain for your pills?

- Very difficult
- Somewhat difficult
- Neutral
- Not very difficult
- Not difficult at all

Rate the extent to which each of the following characteristics of a pill affect the difficulty of taking a pill, where 1 indicates no effect at all and 5 indicates a large effect.

	1 **Does not affect at all**	**2**	**3**	**4**	**5** **Greatly affects difficulty**
Size	◦	◦	◦	◦	◦
Taste	◦	◦	◦	◦	◦
Smell	◦	◦	◦	◦	◦
Shape	◦	◦	◦	◦	◦
Coating	◦	◦	◦	◦	◦
Cost	◦	◦	◦	◦	◦

Please read the following carefully:

The next set of questions pertains to taking pills to PREVENT a heart attack and stroke. Assume that by taking these pills you will live your life free of heart attack and stroke.

Assume that the pills do not cause any side effects and are free of charge. However, you do have to obtain a prescription from your doctor in order to get them, fill the prescription at the pharmacy, remember to take the pill every day, and physically swallow the pill.

Now assume that you have a choice. Instead of taking the pill every day, you could give up time at the end of your life **and also be guaranteed to live a life free of heart attacks and stroke**.

Approximately how much of your remaining life would you give up in order to **NOT** have to take this 1 pill every day for the rest of your life?

- o None
- o 2 weeks
- o 1 month
- o 3 months
- o 6 months
- o 9 months
- o 12 months
- o 18 months
- o 24 months

How about if you were taking two such pills, at the same time of day (for example: 2 pills in the morning)?

- None
- 2 weeks
- 1 month
- 3 months
- 6 months
- 9 months
- 12 months
- 18 months
- 24 months

How about if you were taking two such pills, at two DIFFERENT times of day (for example: 1 pill in the morning, 1 pill at night)?

- None
- 2 weeks
- 1 month
- 3 months
- 6 months
- 9 months
- 12 months
- 18 months
- 24 months

Imagine that you have been diagnosed with a health condition that, if not treated, will limit the quality and length of your life. The physician who diagnoses you tells you that there are two known treatments, **both of which will cure you completely.**

Treatment 1 is a one-time treatment that cures you but happens to also have the potential to cause immediate death.

Treatment 2 is a pill you have to take once a day every day for the rest of your life. There is 0% risk of death from this pill.

Approximately what chance of immediate death are you willing to risk to take Treatment 1 one time instead of taking Treatment 2 every day for the rest of your life?

- 100,000 in 1,000,000
- 10,000 in 1,000,000
- 1,000 in 1,000,000
- 100 in 1,000,000
- 10 in 1,000,000
- 1 in 1,000,000
- 0.1 in 1,000,000
- 0 in 1,000,000

Assume you will work until you are 65 years of age. You can get treatment 1 for a one-time payment. Approximately how much would you be willing to pay to receive Treatment 1 one time instead of taking Treatment 2 every day for the rest of your life?

$_____

Next, we would like to ask you a few questions about chance and working with numbers. For each question, please give us your best estimate, even if you think your estimate is only a guess.

A person taking Drug A has a 1% chance of having an allergic reaction. If 1,000 people take Drug A, how many people would you expect to have an allergic reaction?

# of people = _____

The next question asks how many times something would happen in 1,000 tries.

Example: Imagine picking a jelly bean from a jar filled with an equal number of 4 different colored jelly beans (red, black, blue and green). Out of 1,000 tries, how many times would you expect to pick a red jelly bean?

Answer: 250 times out of 1,000

Now you try: Imagine that we flip a coin 1,000 times. What is your best guess about how many times the coin would come up heads in 1,000 flips?

heads in 1,000 flips = _____

Just a few final questions…

What is your gender?

- o Male
- o Female

What best describes your race/ethnicity?

- o African American
- o Asian
- o Caucasian
- o Native American
- o Pacific Islander
- o Other/None of the above

What is your highest level of education completed?

- Less than high school
- High school or GED
- Some college
- College degree
- Graduate or professional degree

How would you rate your overall health?

- Poor
- Fair
- Good
- Very Good
- Excellent

Do you have health insurance?

- No
- Yes

What is your total household income?

- <$10,000
- $10,000-$24,999
- $25,000-$49,999
- $50,000-$74,999
- $75,000-$99,999
- $100,000-$150,000
- >$150,000